REMARKS/ARGUMENTS

Favorable reconsideration of this application in light of the following discussion is respectfully requested.

Claims 1-7 and 9-16 are now pending in this application. Claim 8 is canceled. Claim 16 is added. Claims 1, 9-11, and 13 are amended. No new matter is added.

In the outstanding Office Action, claims 1-6 and 11-15 were rejected under 35 U.S.C. § 102(e) as anticipated by De Leval, U.S. Patent No. 7,204,802. Claims 1-15 were rejected on the ground of obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,911,003, in view of De Leval.

As amended, claim 1 is directed to a surgical instrument for inserting an implant for treating female prolapse. The surgical instrument includes a handle and a needle portion. The needle portion has a straight portion emerging from the handle and a generally helical portion having a distal end region. The straight portion of the instrument has a longitudinal axis, and the helical portion has an axis that is not parallel to the axis of the straight portion. See, e.g., Figure 1 regarding the axis offset feature. The needle portion is sized and shaped so that the distal end region may initially be moved through a patient's obturator foramen toward the region of the patient's ischial spine, and then toward a vaginal incision in the region of the vaginal apex, so that an implant may be received by the distal end of the needle and moved from the vaginal incision through the patient's obturator foramen. Claims 2-6, 9, and 10 depend directly or indirectly from claim 1.

In contrast thereto, De Leval does not teach or suggest the offset axis feature of claim 1. Instead, De Leval teaches a flat spiral section having an axis that is parallel to the axis of the vertical section 3. Col. 7, line 20 - col. 8, line 18 and Fig 4A. Because the axis of the spiral section is parallel to the attached straight section, De Leval fails to teach the offset axis

limitation. Applicant respectfully requests withdrawal of the rejection of claims 1-6 as anticipated by De Leval.

Claim 11, from which claim 12 depends, is similarly amended, and is directed to an assembly of surgical instruments for treating female prolapse. The assembly includes first and second surgical instruments and an implant. Each of the first and second surgical instrument includes a handle and a needle portion. The needle portions of the respective instruments have the offset axis feature defined by claim 1. One of the surgical instruments has a right handed helical portion, and the other has a left handed helical portion. The needle portions are each sized and shaped so that the distal end region may initially be moved through a patient's obturator foramen toward the region of the patient's ischial spine, and then toward a vaginal incision in the region of the vaginal apex.

As noted above, De Leval does not teach or suggest a surgical instrument having a needle with the offset axis feature defined by claim 1. Accordingly, Applicant respectfully requests withdrawal of the rejection of claims 11 and 12 as anticipated by the De Leval.

Claims 13-15 were also rejected under 35 U.S.C. § 102(e) as anticipated by De Leval. Applicant respectfully traverses these rejections, as the Office has failed to state a prima facie case of anticipation. Claim 13, from which claims 14 and 15 (and new claim 16) depend, is directed to a surgical procedure for correcting vaginal prolapse. The steps include (1) providing a first surgical instrument with a handle and a needle portion, the needle portion having a straight portion emerging from the handle and a generally right handed helical portion at the distal end, (2) providing a second surgical instrument with a handle and a needle portion, the needle portion having a straight portion emerging from the handle and a generally left handed helical portion at the distal end, and (3) providing an implant. The method continues with (4) creating a vaginal incision, (5) incising the patient's skin in the region of the patient's obturator foramen on a first side of the patient, (6) passing the distal

end portion of the first surgical instrument through the obturator foramen and then through the vaginal incision, and (7) associating the implant with the first surgical instrument. Following association of the implant with the first instrument after its traverse from the obturator foramen through to the vaginal incision, the method includes, among other steps, (8) incising the patient's skin in the region of the patient's obturator foramen on the contralateral side relative to the first obturator region incision, (9) passing the distal end portion of the second surgical instrument through the obturator foramen and then through the vaginal incision, and (10) associating the implant with the second surgical instrument.

De Leval does not teach or suggest this surgical method. Specifically, De Leval does not teach or suggest passing the distal end of the surgical instrument through an obturator foramen and then through a vaginal incision. Instead, De Leval teaches passing a needle or introducer from the vaginal incision, through the obturator foramen, to its exit point on the skin near the obturator foramen. Thus, the De Leval method takes the opposite path relative to the path defined by claim 13. Accordingly, the De Leval method cannot anticipate the method of claims 13-15. Applicant respectfully requests withdrawal of these rejections.

Claims 1-15 were rejected on the ground of obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,911,003 ("the '003 patent"), in view of De Leval. This rejection is traversed, as the claims of the '003 patent are directed to a surgical method that does not utilize a needle having a helical portion, as claimed, and the De Leval reference does not teach or suggest the surgical device as presently claimed, in which the needle has a helical portion with an axis that is not parallel to the longitudinal axis of the straight portion of the needle. Further, neither of the cited references teach or suggest the surgical method of the present application. Accordingly, Applicants respectfully request the withdrawal of this rejection, as the claims of the present application are not obvious variations of the claims of the '003 patent, in view of De Leval.

In light of the above discussion, the present application is believed to be in condition for allowance. An early and favorable action to that effect is respectfully requested.

Respectfully submitted,

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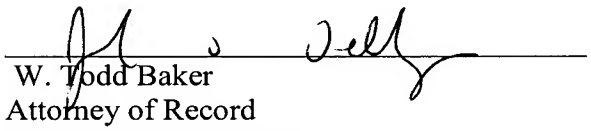

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